K020514

EXHIBIT 2

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Kenneth J. Berk
80 Oakland Street
PO Box 780
Watertown, MA 02472 USA

Telephone: 617-926-6666
Fax: 617-926-6262
ken@pulpdent.com

DEVICE:
Trade Name: ***PULPDENT GLAZE II***
Classification Name: Agent, Tooth Bonding, Resin
FDA Product Code: 76 KLE, 21 CFR Part 872.3200

PREDICATE DEVICE:

Pulpdent Resin Bonding Agent

Bisco Fortify

UltraDent PermaSeal

DESCRIPTION AND INTENDED USE:

Pulpdent Glaze II is a light-cured, unfilled resin that contains no Bisphenol A and is used as a penetrating composite sealer and bonding agent. Pulpdent Glaze II bonds to composite and etched enamel, seals composite margins, penetrates and seals composite surface, reducing micro-leakage, wear and marginal breakdown.

COMPARISON WITH PREDICATE PRODUCTS:

PULPDENT GLAZE II substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above.

SAFETY AND EFFECTIVENESS:

PULPDENT GLAZE II is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above. The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR 872.3200. Though there is no ISO or ANSI/ADA standard applicable to Pulpdent Glaze II, laboratory testing has shown that Pulpdent Glaze II is equivalent in physical and mechanical properties to the predicate products.

According to the NIH Technology Assessment Conference on *Effects and Side-Effects of Dental Restorative Materials*: "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio...both composites and glass ionomers are relatively trouble-free. There is no evidence of short-term or long-term risk...There is no suspicion of any problems after virtually billions of procedures in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2002

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02472

Re: K020514
Trade/Device Name: Pulpdent Glaze II
Regulation Number: 21 CFR 872.3200
Regulation Name: Agent, Tooth Bonding, Resin
Regulatory Class: II
Product Code: KLE
Dated: February 12, 2002
Received: February 15, 2002

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number *(if known)* K020514

Device Name *PULPDENT GLAZE II*

Indications for Use:

Pulpdent Glaze II is a light-cured, unfilled resin that contains no Bisphenol A and is used as a penetrating composite sealer and bonding agent. Pulpdent Glaze II bonds to composite and etched enamel, seals composite margins, penetrates and seals composite surface, reducing micro-leakage, wear and marginal breakdown.

Please do not write below this line. Continue on another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020514

Prescription Use ✓ or Over-The-Counter Use

(Per 21 CFR 801.109)